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K050835

Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda S/5™ Entropy Module, E-ENTROPY and accessories

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

GE Healthcare
86 Pilgrim Road
Needham, MA 02492 USA
Tel: 781-449-8685
Fax: 781-433-1344

NAME OF CONTACT:

Mr. Joel Kent

DATE:

March 30, 2005

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Datex-Ohmeda S/5™ Entropy Module, E-ENTROPY and accessories

COMMON NAME:

Electroencephalograph

CLASSIFICATION NAME:

The following Class II classifications appear applicable:

GWQ	Electroencephalograph	21 CFR 882.1400

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Datex-Ohmeda S/5™ Entropy Module, E-ENTROPY and accessories are substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda M-ENTROPY Module (K023459)

DEVICE DESCRIPTION as required by 807.92(a)(4)

The fundamental scientific technology is identical to the predicate device.
The intended use for the modified device is the same as for the predicate, Datex-Ohmeda M-ENTROPY module and accessories (K023459) The indications for use are also the same.
The Datex-Ohmeda S/5™ Entropy Module, E-ENTROPY is used for acquiring and processing of raw EEG and FEMG signals. The Entropy algorithm processes the collected signals and yields two Entropy variables - state entropy (SE) and response entropy (RE) - and burst suppression ratio, in addition to one real-time EEG waveform channel. The variables may be used as an aid in monitoring the effects of certain anesthetic agents. Entropy is thus used to assess the adequacy of anesthesia status in relation to other standard physiological signs and monitoring modalities (HR, blood pressure, NMT, MAC etc.).
There has been no change to the basic technology from the predicate. The E ENTROPY module is a facelifted version of the predicate M-ENTROPY module. The module cover and mechanics have changed, but the software and measurement hardware are the same as those of the predicate device (K023459).

The Datex-Ohmeda Entropy module, E-ENTROPY is a single-width plug-in parameter module for a Datex-Ohmeda modular monitoring system. The Datex-Ohmeda Entropy module, E-ENTROPY can be used with the following Datex-Ohmeda modular monitors:
S/5™ Anesthesia Monitor (AM) with main software L-ANE03(A)..00 (K030812) or newer version
S/5™ Compact Anesthesia Monitor (CAM) with main software L-CANE03(A)..00 (K041790) or newer version.
The E-ENTROPY module uses the same Entropy algorithm and accessories as the predicate device, M-ENTROPY (K023459).
Entropy is an innovative monitoring modality which is designed to provide information on the electrical activity of the Central Nervous System during general anesthesia. Entropy monitoring is based on acquisition of raw EEG and FEMG signals and processing them by using the Entropy algorithm - a Datex-Ohmeda application of spectral entropy based on information theory. The E-Entropy Module may be used as an aid in monitoring the effects of certain anesthetic agents.
Calculated parameters are:

- Response Entropy, RE (range 0-100), continuous processed variable for fast detection of activation of facial muscles, i.e. FEMG.
- State Entropy, SE (range 0-91), continuous processed variable calculated from the EEG. SE is designed to be sensitive to the hypnotic effect of anesthetic drugs in the brain.
- Burst Suppression Ratio, BSR (range=0-100%), the percentage of epochs in the past 60 seconds in which the EEG signal is considered suppressed.

All the calculated parameters can be selected on the display, and trended.
The raw EEG signal can be displayed from one of the two monitored channels. The waveform size, color and sweep speed can be adjusted.
Alarms for Entropy are taken care of by the host monitor and follow the user interface for alarms in Datex-Ohmeda S/5 patient monitors. There are auditory and visual alarms and user adjustable limits for Entropy variables. The default is OFF, because the device does not provide information to be used for treatment or therapy.
The accessories are the same for the E-ENTROPY module and the predicate device, the M-ENTROPY (K023459). The Datex-Ohmeda Entropy sensor is a rectangular shaped, pre-gelled array of three (3) Zipprep® electrodes that is applied to the patient's skin to record electrophysiological (such as EEG) signals. It is a low impedance, single patient use, disposable electrode sensor that is designed for application to the frontal / temporal area. The Datex-Ohmeda Entropy sensor is designed to provide ease of use and electrode placement accuracy. The sensor is used only with M-ENTROPY and E ENTROPY modules. The Datex-Ohmeda Entropy sensor cable connects the Entropy sensor to the ENTROPY module both mechanically and electrically.

INTENDED USE as required by 807.92(a)(5)

Intended use:
The Datex-Ohmeda Entropy module , E-ENTROPY and accessories are intended to be used with Datex-Ohmeda modular multiparameter monitors for monitoring the neurophysiological status of hospitalized patients.
Indications for use:
The Datex-Ohmeda Entropy Module is indicated for monitoring the state of the central nervous system (CNS) by data acquisition of electroencephalograph (EEG) and frontal electromyograph (FEMG) signals in the anesthesia environment. The spectral entropies, State Entropy (SE) and Response Entropy (RE), are processed EEG and FEMG variables, and may be used as an aid in monitoring the effects of certain anesthetic agents. The Entropy module is indicated for use by qualified medical personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The Datex-Ohmeda S/5™ Entropy Module, E-ENTROPY is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda M- ENTROPY Module (K023459).
The E-ENTROPY module has the following similarities compared to the predicate M ENTROPY (K023459):

- identical intended use and indications for use
- identical fundamental scientific technology
- the same (improved) electronic measurement board
- same (improved) module software (version changed from 1.2 to 1.4)
- same entropy calculation algorithm, with one additional enhancement for demonstrations with awake test persons
- use the same operating principle
- identical accessories
- have the same user interface at the monitor and alarms (can be used with the same monitor software)
- the Customer and parameter specifications are the same
- have the same safety and effectiveness
- are manufactured using the same processes

The main differences between the new E-ENTROPY and the predicate M-ENTROPY (K023459) is primarily due to fact that the new E-ENTROPY module has the following changes:

- New color, shape, and size and thus differing mechanics
- The front panel and labeling have changed
- Minor improvements to the electronic measurement board
- Minor improvements to the module software
- An improvement to the entropy algorithm in the monitor software for demonstration situations with awake test persons.

Based on the analysis and other documentation included in this 510(k) notification and attachments it is evident that the main features and indications for use of the Datex-Ohmeda S/5™ Entropy Module, E-ENTROPY are substantially equivalent to the predicate Datex-Ohmeda M-ENTROPY Module (K023459).

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The Datex-Ohmeda S/5™ Entropy Module, E-ENTROPY and accessories have been assessed against the standards below. The device has been thoroughly tested through validation and verification of specifications.

- FDA/DCRND Reviewer Guidance for Premarket Notification Submissions, November 1993
- IEC 60601-1:1988 + Amdt. 1:1991 + Amdt. 2:1995 (Part 1: General requirements for safety)
- EN 60601-1:1990+ A1:1993 + A13:1996 + A2:1995 (identical to IEC60601-1:1988 + Amdt. 1:1991 + Amdt. 2:1995)
- CAN/CSA C22.2 No. 601.1-M90 + S1:1994 (Canadian deviations to IEC 60601-1:1988 + Amdt. 1:1991) + S2:1998 (=IEC Amdt 2:1995)
- UL 2601-1, October 24, 1997 (U.S. deviations to IEC 60601-1:1988 + Amdt. 1:1991+ Amdt. 2:1995)
- IEC 60601-1-2:2001 (Electromagnetic compatibility – Requirements and tests)
- AAMI ES1-1993 (Safe current limits for electromedical apparatus)
- Electroencephalograph Devices Guidance for 510(k) Content, Draft Document Version 1.0 November 3, 1997
- FDA/ODE Guidance for Content of Premarket Submission for Software Contained in Medical Devices. Version 1.0. (May, 29, 1998)
- IEC 60601-2-26 Medical electrical equipment. Part 2: Particular requirements for the safety of electroencephalographs, 2002.
- ISO 14971 Ed. 1: Medical devices - Application of risk management to medical devices
- FDA Performance standard, 21 CFR Part 898.12 - PERFORMANCE STANDARD FOR ELECTRODE LEAD WIRES AND PATIENT CABLES

CONCLUSION:

The summary above shows that there are no new questions of safety and effectiveness for the The Datex-Ohmeda S/5™ Entropy Module, E-ENTROPY and accessories as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 6 2005

Mr. Joel C. Kent
Manager, Quality and Regulatory Affairs
GE Healthcare
86 Pilgrim Road
Needham, Massachusetts 02492

Re: K050835
Trade/Device Name: Datex-Ohmeda S/5™ Entropy Module, E-ENTROPY and accessories
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: GWQ
Dated: March 31, 2005
Received: April 1, 2005

Dear Mr. Kent:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050835

Device Name: Datex-Ohmeda S/5™ Entropy Module, E-ENTROPY and accessories

Indications for Use:

The Datex-Ohmeda Entropy Module, E-ENTROPY and accessories are indicated for monitoring the state of the central nervous system (CNS) by data acquisition of electroencephalograph (EEG) and frontal electromyograph (FEMG) signals in the anesthesia environment. The spectral entropies, Response Entropy (RE) and State Entropy (SE), are processed EEG and FEMG variables, and may be used as an aid in monitoring the effects of certain anesthetic agents. The Entropy module is indicated for use by qualified medical personnel only.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

...(Sign-Off)

...storative

...Neurological Devices